Complete Summary

GUIDELINE TITLE

Rituximab for the treatment of rheumatoid arthritis.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Rituximab for the treatment of rheumatoid arthritis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 26 p. (Technology appraisal guidance; no. 126).

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- December 18, 2006, Rituxan (Rituximab): Health care professionals informed about important emerging safety information regarding the development of progressive multifocal leukoencephalopathy (PML) in patients under treatment with Rituxan.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Rheumatoid arthritis

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Radiology
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of rituximab for the treatment of severe active rheumatoid arthritis in adults

TARGET POPULATION

Adults with severe active rheumatoid arthritis

INTERVENTIONS AND PRACTICES CONSIDERED

Rituximab in combination with methotrexate for the treatment of adults with severe active rheumatoid arthritis

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Physical function
    - Pain
    - Mortality
    - Quality of life
    - Inhibition of disease progression
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Search Strategy

Direct Comparison

Three electronic databases were searched (Medline, EMBASE and the Cochrane Library) covering the period 1993 to 17th October 2006. In addition, two sets of conference abstracts, European League Against Rheumatism (EULAR) (annual meetings 2002-2005) and American College of Rheumatology (ACR) (annual meetings 2002-2006), were searched via the following websites: http://www.eular.org/ and http://www.rheumatology.org respectively.

Search terms for electronic databases appropriately included a combination of free-text and index terms (rheumatoid arthritis) combined with drug name (rituximab) used as free-text terms. However, the search strategy details do not include any information on the subject index headings (for example, medical subject headings [MeSH]) and the relationship between the search terms (for example, Boolean), details of any additional searches (e.g. searches of company databases).The Evidence Review Group (ERG) was therefore unable to reproduce these searches. However, the ERG is confident that all relevant published trials were identified by the company.

Indirect Comparisons

Searches were conducted focusing on (1) treatment failure and (2) randomised controlled trials (RCTs) of anti-rheumatic drugs that satisfied the following criteria: ACR response criteria as an outcome measure; adult rheumatoid arthritis (RA) patients and trial duration of at least six months. The first search was carried out in Medline (1996 to March Week 4 2005) while the second was carried out in Medline (1966 to March Week 4 2005) and EMBASE (1988 to 2005 Week 21) with additional searches of the Cochrane Library and National Institute for Health and Clinical Excellence Health Technology Assessment (NICE HTA) reports.

For both searches, search strategy details include information on the subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean). However, the search was conducted in April 2005 and has not been updated to inform the current submission (November 2006).

Regarding the first search, the company recognises and discusses the difficulties in targeting a search to the concept of treatment failure due to limited MeSH terms and reliance on text string searching.

Regarding the second search which is limited to RCTs, recognised filters which have been tested, validated and proven to be effective in systematically retrieving RCTs were not utilised.

Inclusion and Exclusion Criteria

Direct Comparison

Details of inclusion and exclusion criteria are provided in Table 3-2 of the ERG Report (see the "Availability of Companion Documents" field) and are considered appropriate and complete.

Indirect Comparisons

Information about the inclusion and exclusion criteria used for the indirect comparisons were not included in the original company submission. However, on request, the company did provide broad reasons as to why papers were excluded from the treatment failure search. For the ACR response criteria search, the company provided the inclusion criteria and broad reasons why studies were included and excluded. The criteria described in Table 3-3 of the ERG Report (see the "Availability of Companion Documents" field) appear to be appropriate.

Application of Inclusion Criteria

Direct Comparison

A flow diagram in the company submission indicates that for direct comparisons, 69 citations were identified by the electronic database search (of which 23 were excluded on the basis of title) and 56 conference abstracts were also identified. One citation and six abstracts describing the phase III, double-blind REFLEX trial (WA17042) and open-label extension to the REFLEX trial (WA17531) met the inclusion criteria set out in the company report.

For the long-term efficacy analyses and safety analyses, the company included data from two phase II RCTs (WA17043 and WA16291); no explanation was given for including additional data sources in their analyses. Both of these trials were appropriately excluded from the systematic review because they included patients who had no prior exposure to a tumour necrosis factor alpha inhibitor(s) (TNFi) and who had received unlicensed doses of rituximab.

Indirect Comparisons

Information provided by the company, upon request, shows the number of results found by each search term and the number of citations excluded by the relevant exclusion criteria; 99/99 citations were excluded for treatment failure leaving no relevant articles; 264 citations were found for ACR response criteria of which 44 were included in the review. However, only six of these studies were used for calculating specific treatment adjusted ACR response rates. The criteria used to select these six studies were not stated. In addition, the company did not provide a flow diagram or present details of the excluded studies or the reasons for their exclusion.

Cost-Effectiveness

Health Economics Literature Search for Rituximab Related Articles

The submission identifies two abstracts describing the cost effectiveness of rituximab in the treatment of rheumatoid arthritis (RA). No details of the search strategy used are provided. The abstracts are neither summarised nor discussed in the submission; the company state that they reflect the economic evaluation in the company submission. Other conference abstracts presented by the company discussing the cost effectiveness of rituximab in RA have also been published but are not identified in the submission.

Health Economics Literature Search for TNFi Related Articles

The company conducted a review which was intended to update and supplement the health economics review that was published in the recent Health Technology Assessment report entitled "A systematic review of the effectiveness of adalimumab, etanercept and infliximab for the treatment of RA in adults and an economic evaluation of their cost-effectiveness". The company did not provide a summary of the methods or the results of this previously published review of the health economics literature.

As part of their review, the company developed a search strategy to "identify economic models, information on costs and cost-effectiveness of TNFi for the treatment of RA"

Identification and Description of Studies

The submission included full details of the electronic search strategy used in the review update. The ERG was therefore able to replicate the electronic searches undertaken by the company. The databases searched were described with dates. The total number of papers initially found and the number of papers excluded from the review were reported. Reasons for excluding papers were also provided.

Stated inclusion criteria were:

Study design: Cost-consequence analysis, cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis, cost studies (UK only), quality of life studies

Population: People with RA; other forms of arthritis are excluded

Intervention: Etanercept, infliximab, or adalimumab

Comparator: Disease modifying anti-rheumatic drugs

Outcome: Quality of life estimates, cost estimates, cost-effectiveness

Time horizon: February 2005 to October 2006

Using these inclusion criteria, the company identified three studies for inclusion in the review; none of the studies included rituximab as a comparator to TNFi.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Direct Comparison

One citation and six abstracts describing the phase III, double-blind REFLEX trial (WA17042) and open-label extension to the REFLEX trial (WA17531) met the inclusion criteria set out in the company report.

For the long-term efficacy analyses and safety analyses, the company included data from two phase II randomised controlled trials (RCTs) (WA17043 and WA16291).

Indirect Comparison

A total of 44 citations was included in the review. However, only six of these studies were used for calculating specific treatment adjusted American College of Radiology (ACR) response rates.

Cost-Effectiveness

Two abstracts on rituximab-related articles

Three tumour necrosis factor alpha inhibitor(s) (TNFi)-related articles

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of Systematic Clinical Review

Key aspects of the methodological quality of the company's review of the clinical literature were assessed based on an accepted quality assessment checklist item and the results are summarised in Table 3-1 of the Evidence Review Group (ERG) Report (see the "Availability of Companion Documents" field).

Quality Assessment

Direct Comparison

The company submission did not include a formal quality assessment but did partly discuss the methodological limitations of the one included trial as specified by NICE. The dates of recruitment and flow diagrams of participants through each stage were unclear. Upon request, the company provided further information on the flow of patients. However, this additional data did not fully explain the flow of patients analysed in the repeat treatment analyses.

The company submission states that this was a blinded study, in which the study sponsor, investigators, and patients were all unaware of the patient's trial arm. A dual assessor approach was employed in which an efficacy assessor only had access to efficacy data while a safety assessor "had access to all clinical and laboratory (safety) data and was able to make any necessary changes to the patient's medical therapy, thus minimizing the chance of unblinding of the efficacy assessor who only had access to efficacy data". Radiographic assessments were collected and scored by two independent readers blinded to treatment assignment and time point.

It is noted that some patients did become unblinded due to vial breakage and it is also stated in the peer reviewed journal article that the blinding of the efficacy assessor was potentially compromised at one of the recruiting centres. While these patients were subsequently excluded from the 24-week intention to treat (ITT) analyses, and a sensitivity analysis demonstrated no change in the significance of the primary results, this issue should be considered when interpreting long-term results that did include these patients.

The quality of data reporting in the company submission was poor: no confidence intervals were presented for any of the results and presentation of p-values was inconsistent.

Indirect Comparisons

The company submission did not provide any quality assessment of the studies included in the indirect comparison analysis. However, it did not acknowledge that the trials included in the indirect comparison analysis (excluding rituximab and abatacept trials) were made up of patients who were from less severe rheumatoid arthritis (RA) populations and not necessarily comparable to the patient population of interest.

Combination of Studies

The company submission states "due to the study selection a meta-analysis was not required". However, analyses of the efficacy of repeated treatments and adverse events do include pooled analyses.

In the analysis of long-term efficacy of repeated treatments, clinical data on 279 patients are analysed in the company submission. However, the actual number of patients from individual trials (WA17043 and WA16291) in the analysis is unclear.

In the analysis of adverse reactions (N=938), data from two Phase II studies are pooled and presented alongside data from the REFLEX trial. In all other safety analyses, an all exposure population (N=1039), from phase II and phase III trials, is described.

Refer to Section 3 of the ERG Report (see the "Availability of Companion Documents" field) for more information.

Cost-Effectiveness

Data Extraction

The company extracted data from the three studies identified for inclusion in the review. The key features of the studies are presented and discussed in the main body of the submission with detailed descriptions of the studies provided in an appendix. In the appendix, details of the three studies are summarised in a format based on a simplified version of the original Drummond and Jefferson checklist for the critical appraisal of published economic evaluations.

Quality Assessment

The submission states that the Consensus on Health Economic Criteria was used to assess the quality of the included studies; it is reported that each study was considered to be of adequate quality as at least 15 checklist points were met by each study. However, the results of the quality assessment conducted by the company are not fully described in the text.

Sensitivity Analysis

Univariate sensitivity analysis and probabilistic sensitivity analysis (PSA) were conducted by the company. The results of the sensitivity analysis (SA) are presented in Table 4-4 of the ERG Report (see the "Availability of Companion

Documents" field). As can be seen from the results of the univariate SA, the model is most sensitive to variations in patient age (Scenario 1) and the assumed interval between those patients who respond to treatment (Scenario 2).

In terms of the PSA, the ERG noted that in the original company submission (based on the original version of the model) the parameter sets are subjected to variations that are governed by the estimated standard deviation of each variable, rather than the standard error of each estimated statistic. The ERG also noted the use of an irregular sampling method from the primary distribution. The ERG concluded that the PSA results (scatterplots and cost-effectiveness analysis curves) should be disregarded as the PSA methodology has not been applied correctly.

Model Validation Reported within the Submission

To determine structural validity, the results of the model were calculated without using model formulae and the expected outputs were compared with the true outputs. The company concludes that all of the cases passed the test with acceptable minimum differences between expected and true outputs. This provides reassurance that no serious formula errors have gone undetected. To determine scenario validity, 16 parameters were changed in the model. The tests revealed two issues; one (negative QALY scores) has been fixed by a change in the programming code and the other (a costing error) has been left unchanged as it has no impact on results.

Refer to Section 4 for further details on cost-effectiveness analyses.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can

comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The manufacturer's submission presented an economic analysis using a microsimulation Markov model based on the REFLEX trial. All patients entered the model at the start of their next treatment option after initial tumour necrosis factor (TNF)-alpha inhibitor therapy had failed. Efficacy estimates were adjusted American College of Rheumatology (ACR) response rates from the indirect comparison. Patient disease progression was tracked within the model according to their health assessment questionnaire (HAQ) score. Baseline HAQ scores and changes in HAQ scores relative to ACR responses were taken from the REFLEX trial. HAQ scores were transposed into quality-adjusted life years (QALYs) by using the Health Utilities Index (HUI)-3 transformation.

The base-case analysis compared rituximab with a return to non-biological disease-modifying anti-rheumatic drugs (DMARDs) following the failure of an initial TNF-alpha inhibitor (scenario 1). It resulted in an incremental cost-effectiveness ratio (ICER) for rituximab of 14,690 pounds sterling per additional QALY. A comparison of rituximab with alternative TNF-alpha inhibitors used sequentially following the failure of an initial TNF-alpha inhibitor (scenario 2) resulted in an ICER of 11,601 pounds sterling per additional QALY.

The Evidence Review Group (ERG) reviewed the economic model and identified two particular issues of concern regarding its implementation. These were the method of randomisation and the representation of parameter uncertainty in the probabilistic sensitivity analysis.

The ERG undertook analysis to assess predominantly the impact of the alternative interpretation of the evidence on the long-term progression rates for HAQ scores. This analysis substantially affected the ICER results. For scenarios 1 and 2, the manufacturer's ICERs increased from 14,694 pounds sterling to 40,873 pounds sterling and from 11,666 pounds sterling to 32,855 pounds sterling per additional QALY respectively.

Following the request of the Committee, the manufacturer carried out analyses of four different variations to the model.

The Committee considered the cost-effectiveness estimates from the manufacturer and the comments of the ERG on this analysis. The Committee noted that scenario 2 (sequential use of TNF-alpha inhibitors following previous treatment failure) was outside current National Institute for Health and Clinical Excellence (NICE) guidance.

The Committee noted that the manufacturer had assumed a constant rate of response for the TNF-alpha inhibitors (and DMARDs) that did not depend on where they were used in the treatment sequence. The Committee was aware that current evidence from the British Society for Rheumatology (BSR) Biologics Register suggests that although people whose first TNF-alpha inhibitor therapy had failed during the first 12 months of treatment were likely to respond to a second agent, on average this was a lesser response than to the first. The Committee discussed whether using an alternative assumption of a reduced response for subsequent TNF-alpha inhibitors would affect the reported ICER for scenario 2. However, the Committee concluded that on the basis of the evidence presented it was unable to determine what effect this may have, and also recognised that the sequential use of TNF-alpha inhibitors was not within current NICE guidance.

The Committee considered the cost effectiveness of rituximab for two sets of differential HAQ progression rates presented by the manufacturer in their original submission and in their clarification. The Committee considered it appropriate to examine primarily the estimates of cost effectiveness based on the differential HAQ progression rates presented in the manufacturer's clarification, to ensure consistency with previous appraisals. The Committee concluded that rituximab is cost effective when using differential HAQ progression rates.

The Committee discussed how best to define initial response to therapy. It was mindful of the fact that the definitions used for describing these responder groups in the manufacturer's original submission did not match those used in other technology appraisals of drugs for the treatment of rheumatoid arthritis. The Committee examined the additional analysis provided by the manufacturer in clarification. The Committee concluded that rituximab is a cost-effective use of National Health Service (NHS) resources when the initial response is defined as an improvement in disease activity score (DAS28) of 1.2 points or more.

Refer to Sections 3 and 4 of the original guideline document for additional information.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Rituximab in combination with methotrexate is recommended as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to or intolerance of other disease-modifying anti-rheumatic drugs (DMARDs), including treatment with at least one tumour necrosis factor alpha (TNF-alpha) inhibitor therapy.

Treatment with rituximab plus methotrexate should be continued only if there is an adequate response following initiation of therapy. An adequate response is defined as an improvement in disease activity score (DAS28) of 1.2 points or more. Repeat courses of treatment with rituximab plus methotrexate should be given no more frequently than every 6 months.

Treatment with rituximab plus methotrexate should be initiated, supervised and treatment response assessed by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of rituximab for the treatment of rheumatoid arthritis in adults

POTENTIAL HARMS

The most commonly reported adverse reactions are acute infusion reactions or infections and infestations (mainly upper respiratory tract infections).

For full details of side effects and contraindications, see the summary of product characteristics (SPC).

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications for the use of rituximab are hypersensitivity to the active substance; active, severe infections (including tuberculosis, sepsis and opportunistic infections); and severe heart failure or severe uncontrolled cardiac disease.

For full details of side effects and contraindications, see the summary of product characteristics (SPC).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- The Evidence Review Group (ERG) identified problems with the company submitted economic model in two stages. Early examination of the submitted

economic model by the ERG identified some aspects of its implementation, which caused concern as to its reliability for generating estimates of cost-effectiveness. The company then submitted a revised model and addressed some of the ERG's concerns. However, the ERG subsequently identified a number of additional clinical and economic issues that call into question the validity of key assumptions in the revised economic model, and the credibility of the incremental cost-effectiveness ratios (ICERs) generated. In particular, the ERG questions whether the size of benefit from each rheumatoid arthritis treatment is overstated, because loss of efficacy is assumed to be instantaneous rather than cumulative. This assumption merits further justification from the company. The ERG concludes that the robustness of the evidence base used in the company economic model is uncertain.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for Better Health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- 'Healthcare Standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on NICE website (www.nice.org.uk).
    - Costing statement incorporating a costing report to estimate the savings and costs associated with implementation
    - Audit criteria to monitor local practice

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Rituximab for the treatment of rheumatoid arthritis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 26 p. (Technology appraisal guidance; no. 126).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Aug

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Jeff Aronson, Reader in Clinical Pharmacology, Radcliffe Infirmary; Dr Darren Ashcroft, Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Professor David Barnett (Chair), Professor of Clinical Pharmacology, University of Leicester; Dr Peter Barry, Consultant in Paediatric Intensive Care, Leicester Royal Infirmary;

Professor Stirling Bryan, Director of the Health Economics Facility, University of Birmingham; Professor John Cairns, Public Health and Policy, London School of Hygiene and Tropical Medicine; Dr Mark Charkravarty, Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK) Ltd, Professor Jack Dowie, Health Economist, London School of Hygiene and Tropical Medicine; Lynn Field, Nurse Director; Pan Birmingham, Cancer Network; Professor Christopher Fowler, Professor of Surgical Education, University of London; Dr Fergus Gleeson Consultant Radiologist, Churchill Hospital; Ms Sally Gooch Former Director of Nursing & Workforce Development, Mid Essex Hospitals Services NHS Trust; Mrs Barbara Greggains, Company Director, Greggains Management Limited; Mr Sanjay Gupta, Former Stroke Services Manager, Basildon and Thurrock Universities Hospitals NHS Trust; Dr Mike Laker, Medical Director, Newcastle Hospitals NHS Trust; Mr Terence Lewis, Mental Health Consultant, National Institute for Mental Health in England; Professor Gary McVeigh Professor of Cardiovascular Medicine, Queens University, Belfast; Dr Ruairidh Milne, Senior Lecturer in Health Technology Assessment, National Coordinating Centre for Health Technology; Dr Neil Milner General Medical Practitioner, Tramways Medical Centre, Sheffield; Dr Rubin Minhas, General Practitioner, CHD Clinical Lead, Medway PCT; Dr John Pounsford, Consultant Physician, North Bristol NHS Trust; Dr Rosalind Ramsay, Consultant Psychiatrist, Adult Mental Health Services, Maudsley Hospital; Dr Stephen Saltissi, Consultant Cardiologist, Royal Liverpool University Hospital; Dr Lindsay Smith, General Practitioner, East Somerset Research Consortium; Mr Cliff Snelling, Lay Member; Professor Andrew Stevens, Professor of Public Health, University of Birmingham

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Rheumatoid arthritis (refractory) – rituximab. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug 22. 2 p. (Technology appraisal 126). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Rheumatoid arthritis (refractory) – rituximab. Costing template and report. London (UK): National Institute for Health and Clinical Excellence (NICE);

2007 Aug. 19 p. (Technology appraisal 126). Available in Portable Document Format (PDF) from the NICE Web site.

- Rheumatoid arthritis (refractory) – rituximab. Audit criteria. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug 22. 10 p. (Technology appraisal 126). Available in Portable Document Format (PDF) from the NICE Web site.
- Rituximab for the treatment of rheumatoid arthritis. Evidence Review Group report. Liverpool Reviews and Implementation Group; 2007 Mar 30. 213 p. (Technology appraisal 126). Available in Portable Document Format (PDF) from the NICE Web site.
- Guide to the single technology appraisal process. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sept 19. 44 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: TA126. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Rheumatoid arthritis (refractory) – rituximab. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug 22. 4 p. (Technology appraisal 126).

Available in Portable Document Format (PDF) from the NICE Web site.

NGC STATUS

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Date Modified: 9/29/2008